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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/415,890 10/08/99 ANDERSSON

B UTXC:528--1

EXAMINER

HM12/0924

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LEVY, N

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

09/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

09

Application No.

415890

Applicant(s)

ANDERSON et al

Examiner

Milley

Group Art Unit

1616

8

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 6/19/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 16-23, 26-80 is/are pending in the application.
- Of the above claim(s) 16-23, 49, 69-80 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 26-48, 50-80 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1616

Receipt is acknowledged of Amendment of 6/19/01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-23, 49, 69-80 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Claims 26-48, 50-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The lyophilization virtually eliminates DMA, is supported/applicant's arguments, at p. 17, top. However, claim 26 is contradictory, (it is a solvent vehicle, a composition) as it both claims the solvent, and disclaims the solvent. One in the art would not know how to provide (p. 4, lines 20-22) an aprotic solvent vehicle, substantially free of the aprotic solvent. The claim 68 lyophilized product is no longer a vehicle.

Claims 26-48, 50-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language (above) is contradictory. In claim 34, 47 "lipid solution" would not constitute an aqueous solvent further description is required; also differentiation from lipid

Art Unit: 1616

emulsion. "Substantially" is not in the specification; "virtually" is. In claim 49, we no longer have a vehicle; we now have drugs and carriers and adjuvants; this is not a vehicle, and so is withdrawn as a drug composition of Group III. The rejection to claim 65 and 6 is withdrawn; 66 is seen as limiting 65. Claim 68 has no antecedent support, as it is written: claim 26 is to a vehicle, not found in the lyophilized vehicle? Of claim 68. Examiner questions; if lyophilized, what is the vehicle? We see no vehicle--this claim is referrant to the liposymer intralipid formulations, so far as examiner can determine.

Claims 26-28, 30-34, 41-45, 47, 48, 50-59 and 63-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson-5559148 or 5430857.

The rejection of record is maintained.

Now, only an aqueous vehicle is required to meet the claims (free of organic solvent).

Claims 26-27, 29, 32, 34-35, 37-42, 47, 48, 63-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugiyama et al 5651991.

The rejection of record is maintained.

Claims 26-48, 50-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al 5430057 in view of Sugiyama.

The rejection of record is maintained.

Applicant's arguments filed 6/19/01 have been fully considered but they are not persuasive.

Applicant's arguments are persuasive to the extent indicated by dropping of 112 issues.

Art Unit: 1616

However, the claims require no more than trace amounts of solvent, and as such prior art meets them.

Claims 26-28, 30, 34, 36, 41, 47, 48, 52, 63-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Szoka et al 5277914.

See col. 3, 4, 5 lipids and aqueous (lower alcohol) co-solvents are used as vehicles for drugs.

Claims 26, 30, 34, 42, 63-65, 67, 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Pallado et al WO 96/29998.

See p. 13: Aqueous buffer and DMSO (Example 1) are lyophilized. There is no solvent left. See p. 25 for intended drugs, or claim 5. See p. 35--pharmaceuticals.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1616

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

September 14, 2001



NEIL S. LEVY  
PRIMARY EXAMINER